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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,645

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EXAMINER

KOSAR, AARON J

ART UNIT

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1651

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/598,645	<b>Applicant(s)</b> CANDUSSIO ET AL.	
	<b>Examiner</b> AARON J. KOSAR	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 9-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/2/06</u>   | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Claims 9-21 are pending and have been examined on the merits.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 9-21** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9-21 are incomplete for omitting essential steps. While all of the technical details of a method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is to be practiced. The minimum requirements for method steps minimally include a *providing/contacting step* in which the reaction of the sample with the reagents necessary for the reaction is recited, an *effecting/detecting step* in which the reaction steps are quantified or visualized, and a *correlating/concluding step* describing how the results of the reaction allow for the determination. In these claims, the *correlating/concluding* step is missing, because the claims do not recite how the incubation or the conditions thereof provide for a product composition or the correlated minimal structural features by which the product may be identified as qualifying as a biologically decomposed material.

Claim 10 is rejected because the term “fragment thereof” is indefinite. The term is indefinite, because a fragment of a compound includes numerous chemical transformations of the compound, including among other “fragments” individual elements and subatomic particles that comprise the claimed composition. Thus one would not be apprised as to the compositions embraced by the term, thereby rendering the claim indefinite.

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In claim 10 Applicant fails to set forth the criteria that define a “polyorganosiloxane”, “organofunctional siloxane”, or “organosilanol” other than providing a functional definition of “polyorgano-”, “organofunctional-”, and “organo-” compounds as “liquid” or “solid” (e.g. ¶3, page 3). Such functional language describes nothing about the chemical, physical, or structural properties of these compounds. Attention is directed to *General Electric Company v. Wabash Appliance Corporation* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed.: “the vice of a functional claim exists not only when a claim is ‘wholly’ functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty”. Functional language at the point of novelty is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does “little more than outline goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate”. Claims employing functional language at the point of novelty neither provide those element required to practice the invention, nor “inform the public during the life of the patent of the limits of the monopoly asserted.”, *General Electric Co. v. Wabash Appliance Corp.*, at 468.

In spite of applicant's arguments to substantiate the claimed process as unobvious, insofar as these processes rely on the use of components which instead of being characterized by technical features suitable for the identification of a component, is imprecisely defined by means of functional features which merely recite the desired result to be achieved, the subject matter is still considered to be obvious by the disclosures of the prior art.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 9-21** are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a sewage sludge culture and for a reduction in DMSD or D4 concentrations, does not reasonably provide enablement for all microorganisms/populations, reactions, and/or products. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in *Wands* states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

*(1) The nature of the invention and (2) the breadth of the claims:*

The claims are drawn to a mixture of a material comprising a silicon-carbon single bond and a microorganism population to obtain an undisclosed product/result by the use of a non-oxygen electron acceptor. The specification is drawn to providing a resuspended culture of sewage sludge in the presence of  $\text{KNO}_3$  to obtain reduced levels of DMSD or D4 as measured by

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<sup>1</sup>H-NMR (D<sub>2</sub>O) and GC-FID, respectively. Thus, the claims taken together with the specification imply a breadth greater than what is supported by the specification.

*(3) The state of the prior art and (4) the predictability or unpredictability of the art:*

The art is such that the *a priori* identity of all organisms capable of functioning in the manner claimed and of all reactions and providing the myriad of desired products of desired structure and function resulting from incubating remains largely unsolved, thus means for determining is highly unpredictable.

*(5) The relative skill of those in the art:*

The relative skill of those in the art is high with respect to obtaining/incubating samples; however, with respect to identification of all organisms, reactions, transformations, and products therefrom capable of functioning in the claimed manner, is beyond the purview of one of skill.

*(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:*

The specification has provided limited species to the extent of the two (2) working examples comprising in general contacting sludge sample broth with DMSD or D4 in the presence of KNO<sub>3</sub>; however, the specification does not provide working examples representative of the genera of all Si-C containing compositions, all microorganisms, all conditions, or all electron acceptors.

*(8) The quantity of experimentation necessary:*

Considering the state of the art, the high unpredictability, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to make and use the invention to the extent instantly claimed.

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It is the Examiner's position that one skilled in the art could not practice the invention commensurate in the scope of the claims without undue experimentation.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 9, 10, 12-14, and 16-17** are rejected under 35 U.S.C. 102(b) as being anticipated by GRÜMPING (6:IDS).

The claims are generally drawn to a method comprising anaerobically or micro-aerobically incubating a Si-C material and a microorganism in the presence of an alternative (i.e. non-oxygen) electron acceptor.

GRÜMPING (6) anticipates the claims by teaching treating sewage sludge samples and sewage sludge samples comprising octamethylcyclotetrasiloxane (D4). Grüpming also teaches that “viable cells are necessary for degrading D4” and “demonstrated that low-molecular-weight siloxane D4 is susceptible to anaerobic degradation by sewage microorganisms under anaerobic conditions”(page 2277, ¶ 5; page 2276, ¶4). The D4-containing/spiked sludge was degassed and incubated at 37°C in an anaerobic container having a 20% CO<sub>2</sub> and 80% H<sub>2</sub> anaerobic atmosphere (page 2277, ¶1) whereby the D4 biodegraded to provide a net increase in DMSD followed by a net decrease in DMSD concentration (e.g. Figure 2).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 9-21** are rejected under 35 U.S.C. 103(a) as being unpatentable over GRÜMPING (6:IDS) and HINCE (US 6,020,185), in view of WATTS (3:IDS).

The claims and GRÜMPING (6) are as presented above.

HINCE teaches anaerobic remediation of a geological material comprising providing a material, including sludge (column 2, line 10) and culturing multiple respiration pathway (MRP) microbes. Nutrients and electron acceptors are also provided, including nitrate which is provided to provide a nitrogen source and an electron acceptor (table 1; column 4, ¶7; column 9, ¶7 and portion spanning column 10). Hince also beneficially teaches that delivery of nutrients, electron acceptors, and inert carrier gas results in the effect to “promote conditions favorable to growth”(column 4, ¶2).

To the extent that Hince may be silent with respect to a Si-C containing composition, as evidenced by WATTS (3), “Pallenbarg showed [PDMS and its oligomers] to be present in sludge fractions” (Watts, page 2405, ¶2). Thus, Watts teaches that sludge intrinsically comprises the above polysiloxanes, or in the alternative, it would have been obvious to have provided a



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polysiloxane-containing sludge, since the compositions have the same minimal structural/compositional features (sludge in contact with anaerobic microorganisms) and are treated in the same manner (anaerobic, biodegrading incubation/stimulation) to the extent instantly claimed (e.g. column 14, ¶1) and thus would be expected to provide the same product/result to the extent claimed, especially in the absence of objective evidence to the contrary.

To the extent that Grümping may be silent with respect to the addition of an electron acceptor, it would have been obvious to have provided an electron acceptor to an anaerobic composition, because Hince teaches that electron acceptors and their hierarchical solubilities,  $\Delta G$ 's, and function are known. One would have been motivated to have provided an electron acceptor, including a nitrate electron acceptor, because Hince teaches that the electron acceptors promote conditions favorable to growth; and, because relative to the aerobic electron acceptor  $O_2$ ,  $NO_3^-$  has the greatest solubility and  $\Delta G$  versus the other electron acceptors ( $NO_3^- > Fe^{+3} > SO_4^{2-} > CO_2$ ; see e.g. table 1). One would have had a reasonable expectation of success in providing the electron acceptors, because Hince teaches that the sequence is that preferred by nature and that nitrate and sulfate are much more soluble, less reactive, and more mobile in water than oxygen (column 8), and especially in the absence of objective evidence to the contrary.

To the extent that Grümping or Hince may be silent with respect to a particular condition, it would have been obvious to one skilled in the art at the time of invention to determine all optimum and operable conditions (e.g. time/extent of reaction, temperature, concentration/proportion of reagents), because such conditions are art-recognized result-effective variables that are routinely determined and optimized in the art through routine experimentation. ("[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to

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discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). *See* MPEP § 2145.05).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion of Grümping or of Hince/Watts, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

To the extent that the above arguments may rely in part upon compositions of the prior art processes versus those provided in the instantly claimed method, please note, since the Office does not have the facilities for examining and comparing Applicants' composition with the compositions of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. *See In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980), and "as a practical matter, the Patent Office is not equipped to manufacture products by the myriad of

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processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

GRIESSBACH (U:PTO-892: Griessbach, E.F.C. and Lehmann, R. G. "Degradation of Polydimethylsiloxane Fluids in the Environment - a Review" *Chemosphere*, 1999, Vol. 38, No. 6, pp. 1461-1468.) *considered relevant in teaching soil decomposition of sludge siloxanes and silanol facilitated by biodegradation (e.g. figures 1-3; abstract) and teaching the state of the art in general.*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. KOSAR whose telephone number is (571)270-3054.

The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday,EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sandra Saucier/  
Primary Examiner, Art Unit 1651

/Aaron J Kosar/  
Examiner, Art Unit 1651